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| EXAMINER | | | | |
| SASAKI, SHOGO | | | | |
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/520,074

Applicant(s)

MCEWAN ET AL.

Examiner

Shogo Sasaki

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 11 October 2005.
2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-6 is/are pending in the application.
4a) Of the above claim(s) _____ is/are withdrawn from consideration.
5) ☐ Claim(s) _____ is/are allowed.
6) ☒ Claim(s) 1-6 is/are rejected.
7) ☒ Claim(s) 1 and 6 is/are objected to.
8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
10) ☒ The drawing(s) filed on 05 January 2005 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/5508)
Paper No(s)/Mail Date 10/11/2005
4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____

DETAILED ACTION

Specification

1. The specification is objected to as failing to provide proper antecedent basis for the claimed subject matter. See 37 CFR 1.75(d)(1) and MPEP § 608.01(o). Correction of the following is required: Claim 1 recites limitation "amplifying the amount and rate of ethylene produced in ..." in line 13. There is no specific disclosure of how such step is performed so in the specification. Appropriate correction is required. No new matter should be entered.

Claim Objections

2. Regarding the recitation "the measuring" in line 2 of claim 1, it is suggested replace "the measuring" with "a measurement."

Regarding claim 1, it is also suggested to add activities after "the oxidative free radical."

Also regarding claim 1, it is suggested to replace "introduced analyte antioxidant activity" with "antioxidant activity of the analyte."

Claim Rejections - 35 USC § 112

3. The following is a quotation of the second paragraph of 35 U.S.C. 112:
The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

4. **Claim 1-6** are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Regarding claim 1:

The recitation "the carrier gas/ion stream" in line 10 renders said claim indefinite, because it is not clear if it is same as carrier gas stream recited in line 9 of said claim or some other ion/gas mixture. It is suggested to replace "the carrier gas/ion stream" with said stream of inert carrier gas, or to define a carrier gas/ion stream earlier in the claim. Claim 4 also recites the same limitation, and

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must be corrected. Appropriate correction is required. No new matter should be entered.

The recitation "the analyte" in line 6 renders said claim indefinite, because it is not clear if it is same as "ethylene" recited in line 5, or some other item. Appropriate correction is required. No new matter should be entered.

The recitation "the substrate" in line 7 renders said claim indefinite, because it is not clear if it is "a substance" recited in line 2 of said claim or some other item. Appropriate correction is required. No new matter should be entered.

The recitation "an assay" in line 5 renders said claim indefinite, because it is not clear if it is the same as "a method of determining, measuring and comparing ..." recited in line 1 of said claim or some other procedure. Appropriate correction is required.

The limitation "the reaction mixture head space" in line 11 and 14 has insufficient antecedent basis. It is suggested to replace "the reaction mixture head space" with appropriate items from the preamble, or to define a reaction mixture head space earlier in the claim.

Examiner strongly suggests applicant to rewrite the preamble of claim 1. The recitation of "including" and "comprising" before "the method comprising" at the end of the preamble; and aforementioned issues render the claim indefinite, because it is not clear what items and what steps are involved in said method; and what items are involved in recited steps. The correction must also fix the 112 (2) rejections listed above and also below, and provide proper antecedent basis to the limitations recited in the body of claim 1 and in the claims which depend from claim 1. No new matter should be entered.

Claim 2 recites the limitation "the trace elements." There is insufficient antecedent basis for this limitation in the claim. It is suggested to define trace elements earlier in the claim.

Claim 2 also recites the limitation "the helium stream." There is insufficient antecedent basis for this limitation in the claim. It is suggested to specify inert

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carrier gas as a helium stream earlier in the claim, or to define a helium stream earlier in the claim.

Claim 3 recites the limitation "the measurement of the rate and amount of introduced analyte." There is insufficient antecedent basis for this limitation in the claim. It is suggested to replace said limitation with "the measurement of the rate and amount of introduced analyte antioxidant activity."

Claim 5 recites the limitation "each gas species of volatile organic compounds in **the gas mixture**." There is insufficient antecedent basis for this limitation in the claim. It is suggested to define a gas mixture earlier in the claim.

Regarding claim 6, the recitation "a second mass filter" renders the claim indefinite, because the recitation of "a second" implies there is a first mass filter. However said claim does not recite another mass filter.

Claim Rejections - 35 USC § 103

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

6. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

7. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any

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inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

8. **Claims 1-6** are rejected under 35 U.S.C. 103(a) as being unpatentable over Winston et al. (Free Radical Biology & Medicine, Vol. 24, No. 3, pp. 480-493, 1998) in view of Wilson et al. (IDS: Journal of American Society of Mass Spectrometry, vol. 13, pp. 1028-1033, 2002).

Regarding claim 1, Winston et al. disclose a method of determining, measuring and comparing the oxidative radical activity in a natural or synthetic substance (abstract), comprising measuring the concentration of ethylene as an assay for antioxidant activity to provide a measurement of the concentration of the analyte to thereby indicate the total activity of an antioxidant and the rate of reaction of the antioxidant with the substrate (abstract: The chemical species involved in the assay are identical to the ones disclosed in the instant application.).

Although Winston et al. teach the method of assaying the anti-oxidation and scavenging activity of a substance claimed and disclosed by the applicant, Winston et al. do not employ mass spectroscopy in their assay. Winston et al. use an analysis via gas chromatography to monitor the formation of ethylene in the head space from the reaction vessel (abstract).

Wilson et al. show a use of SIFT-MS technology to detect trace levels of compounds by monitoring chemical reactions between ionized species with hydrocarbons and trace levels of compounds (abstract, line 11-12). Wilson et al. teaches:

producing, mass selecting and accelerating precursor ions into a stream of inert carrier gas (page 1029, Experimental section, line 1-13);

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injecting a mixture of the gas sample and the analyte into the carrier gas/ion stream (page 1029, Experimental section, line 1-13);

allowing the substrate in the reaction mixture head space to react with the selected precursor ions (abstract; and page 1029, Experimental section);

detecting and analyzing the amount and rate of byproduct produced in the reaction mixture headspace as a measure of the rate and amount of introduced analyte reactivity (Table 1).

It would have been obvious to one having ordinary skill in the art at the time of the invention to employ SIFT-MS technology in place of gas chromatography to monitor reaction between the antioxidant and the substrate by detecting byproduct (ethylene) as taught by Wilson, for the purpose of quantitatively measuring (as opposed to confirming the existence of a compound by studying the peak in chromatogram) the trace amount of byproduct produced, because the measurement of antioxidant activity is solely based on the concentration of byproduct which may be small.

The claim would have been obvious because a particular known technique was recognized as part of the ordinary capabilities of one skilled in the art; and because "a person of ordinary skill has good reason to pursue the known options within his or her technical grasp. If this leads to the anticipated success, it is likely the product not of innovation but of ordinary skill and common sense."

Regarding claims 2-6, Wilson et al. further teaches that the trace elements in the gas sample react with the precursor ions in the helium stream (page 1029, Experimental section, line7);

wherein the partial pressure of byproduct in the gas sample is calculated as part of the measurement of the rate and amount of introduced analyte (The total pressure of the gas is held constant (page 1029, Experimental section, line 11) and the concentration of byproduct can be measured from the result, therefore the partial pressure must have been able to be calculated/measured from the known parameters via Daltons law.);

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wherein the gas sample is introduced into the carrier gas/ion stream (page 1029, Experimental section) at a calibrated rate (page 1029, Experimental section, line 14) via a heated capillary inlet (page 1029, Experimental section, line 13, venturi orifice);

wherein the concentration of each gas species of volatile organic compounds in the gas mixture is calculated from the number densities of the precursor and product ions (page 1029, column 2, lines 11-13; and Table 1 shows reaction rate coefficients and product ratios for the reactions of ionic species and the substrate.); and

wherein the number densities are measured by a mass filter (page 1029, Experimental section, line 7) in conjunction with a particle multiplier (page 1029, Experimental section, line 11, ion lens: a particle multiplier is a part of mass spectrometer), and a software interface (a mass spectrometer will have to be provided with a computer interface.).

Conclusion

9. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Shogo Sasaki whose telephone number is (571)270-7071. The examiner can normally be reached on Mon-Thur, 10:00am-6:30pm, EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jill Warden can be reached on 571-272-1267. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Yelena G. Gakh/
Primary Examiner, Art Unit 1797

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1/2/2009